B7 37(8)

30. (amended) [A birnavirus] The IBDV according to claim 6, [wherein the IBDV] which expresses a chimeric VP2 protein comprising neutralizing epitopes of different antigenic IBDV types.

Claim 31, in each of lines 1 and 2, please change "a birnavirus" to -- an IBDV --; and

line 3, please change "22 - 30" to -- 24 - 30--.

## **REMARKS**

Claims 1 - 4, 6 - 10, 12, 15, 17, 18 and 24 - 31 are amended and claims 5, 22 and 23 are canceled. Claims 1 - 4, 6 - 10, 12, 13, 15 - 21 and 24 - 31 are now pending.

In the Office Action, claims 1 - 4, 10, 22, 24, 26, 28 and 31 were rejected under §112, first paragraph, for alleged non-enablement of the full scope of the claims.

Concerning the first issue in this rejection, the claims have now been limited to IBDV. Concerning the second issue, the Examiner appears to object to the term "native", because she does acknowledge that the specification provides "an adequate description of mutant IBDV, mutations which delete VP5 sequences, insert homologous sequences, or substitute heterologous sequences for VP5". If this is indeed the case, Applicants may consider deleting the term "native". On the other hand, if the Examiner is objecting on the basis of non-enablement or lack of written description for an IBDV mutant which is not able to produce a (09/084,837)

native VP5 protein as a result of substitution in the VP5 gene, Applicants have the following response.

Whereas IBDVs isolated from the field, hitherto, are found to express to a VP5 protein, the claimed IBDV mutants are not able to express a VP5 protein, which is generally expressed by the prior art IBDVs. This can be the result a mutation in the VP5 gene which completely prevents the expression of any VP5 sequences, or may be the result of a mutation in the VP5 gene which causes the expression of only a part of the naturally-expressed VP5 protein. As evidence that Applicants had the invention as claimed in claim 2, for instance, in their possession, Applicants refer to:

- (1) page 5, lines 11 22 and SEQ ID NO. 3 and 4, disclosing the nucleotide and amino acid sequence of the VP5 gene/protein of IBDV;
- (2) page 6, lines 20 32, stating that the preferred mutation in the framework of this invention is a substitution of one or more nucleotides in the VP5 gene of the IBDV;
- (3) in Example 1, the preparation of two different IBDV mutants according to claim 2, that is, IBDV/VP and IBDV/VP5 2 are described (see also Figures 2 and 3). Both these IBDV mutants are mutants according to claim 2, which comprise several substitution mutations as a result of which these mutants are not able to express a native VP5 protein;

(4) the biological properties of both IBDV substitution mutants are examined in animals experiments (Examples 3 and 4 respectively).

In view of the above, it is clear that the invention as described in claim 2 was in the possession of the inventors at the date of filing this application.

The above amendments and remarks are responsive to the §112, first paragraph, rejections appearing on pages 2 and 3 of the Office Action. It is courteously requested that these rejections be reconsidered and withdrawn.

Claims 15, 28, 29 and 31 were rejected under §112, first paragraph, for alleged nonenablement of strain D78. It is the Examiner's position that strain D78 is required to practice the invention. However, Applicants refer to the following:

- (1) SEQ ID NOs:3 8, which show the DNA sequence of the D78 genome, including the VP5 nucleotide, and the corresponding the amino acid sequence information.
- (2) The assignee's U.S. Patent No. 4,530,831, directed to the IBDV D78 strain, a copy of which is provided.
- (3) The attached commercial brochure of Intervet, Inc.
  (U.S.) and Intervet International B.V. (European), demonstrating the general availability of D78 based vaccines.

Accordingly, the materials necessary to practice the present invention as claimed were publicly available.

Finally, claim 1, 12, 13 and 16 - 21 are rejected under

§102(b) over Heppell et al. This rejection is considered moot in view of the foregoing amendments to the claims. Withdrawal is deemed proper.

A substitute paper copy and CRF of the sequence listing is provided herewith.

Should the Examiner believe any minor issues remain that could be resolved by a telephone conference, she is invited to contact the undersigned at the number listed below.

A petition for extension of time accompanies this paper.

If any other fees are due in this application, please charge our

Deposit Account No. 02-2334.

Respectfully submitted,

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Enclosures: Sequence Listing (Paper copy & Diskette)

Copy of Notice to Comply U.S. Patent No. 4,530,831

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